

AMENDED IN ASSEMBLY APRIL 10, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 1437

Introduced by Assembly Member Koretz

February 21, 2003

An act to add Article 6 (commencing with Section 110424.8) to Chapter 4 of Part 5 of Division 104 of the Health and Safety Code, and to add Section 14105.37 to the Welfare and Institutions Code, relating to drug marketing practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 1437, as amended, Koretz. Drug marketing practices.

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains various provisions regarding the packaging, labeling, and advertising of food, drugs, and cosmetics. A violation of any of these provisions is punishable as a misdemeanor, *and shall also subject the violator, upon conviction, to a fine in the amount of \$1,000, or if the violation is committed after a previous conviction has become final, to a fine in the amount of \$10,000.*

This bill would make it unlawful, under that law, for any person to engage in inappropriate marketing of any drug or device ~~used in the treatment of life-threatening chronic conditions~~ to physicians or other medical providers. *It would also provide, notwithstanding the above penalty provisions, that violations of this provision or related regulations shall subject the violator, upon conviction, to fines of up to \$20,000 per violation, as specified.*

~~This bill would also require every pharmaceutical manufacturing company to disclose to the State Department of Health Services the~~

~~value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with certain drug marketing activities, with certain exceptions.~~

This bill would create a new crime, thereby imposing a state-mandated local program.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on a Medi-Cal list of contract drugs, and obtains best price rebates from drug manufacturers.

This bill would require the department, during each negotiation with a manufacturer regarding the purchase ~~price of a drug or of one or more drugs or devices~~ used to treat a life-threatening condition, *as defined*, to require the manufacturer to disclose the aggregate marketing costs for the ~~drug or drugs or devices~~ that are the subject to the negotiation.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Article 6 (commencing with Section 110424.8)
2 is added to Chapter 4 of Part 5 of Division 104 of the Health and
3 Safety Code, to read:

4
5 Article 6. Drug Marketing Practices

6
7 110424.8. (a) It is unlawful for any person to engage in
8 inappropriate marketing of any drug or device ~~used in the~~
9 ~~treatment of life-threatening chronic conditions~~ to physicians or
10 other medical providers.

11 (b) For purposes of this section, “inappropriate marketing”
12 means any action intended to entice a physician or other medical



1 provider to employ a drug or device in the treatment of a patient
2 by offering any of the following:

3 (1) Cash payments to physicians of any kind.

4 (2) Gifts to physicians that are not directly related to the benefit
5 of the patient or the practice of the physician related to the drug or
6 device.

7 (3) Travel, meals, or lodging for the physician unless they are
8 associated with legitimate physician education.

9 (4) Any payment or subsidy for other cost that is not directly
10 related to the benefit of the patient or the practice of the physician
11 related to the drug or device.

12 ~~(e) For purposes of this section, “life-threatening chronic~~
13 ~~condition” means a condition or disease that requires specialized~~
14 ~~medical care over a prolonged period of time and will result in~~
15 ~~death within five years without an appropriate drug regimen.~~

16 ~~110424.85. (a) Every pharmaceutical manufacturing~~
17 ~~company shall disclose to the department, on a quarterly basis, the~~
18 ~~value, nature, and purpose of any gift, fee, payment, subsidy or~~
19 ~~other economic benefit provided in connection with detailing,~~
20 ~~promotional, or other marketing activities by the company,~~
21 ~~directly or through its pharmaceutical marketers, to any physician,~~
22 ~~hospital, nursing facility, pharmacist, health benefit plan~~
23 ~~administrator or any other person in California authorized to~~
24 ~~prescribe, dispense, or purchase prescription drugs in this state.~~
25 ~~Disclosure shall be made on a form and in a manner prescribed by~~
26 ~~the department.~~

27 ~~(b) Each company subject to the requirements of subdivision~~
28 ~~(a) shall also disclose to the department annually the name and~~
29 ~~address of the individual responsible for compliance with that~~
30 ~~subdivision.~~

31 ~~(c) The department shall keep confidential all trade secret~~
32 ~~information disclosed to the department pursuant to subdivision~~
33 ~~(a). The disclosure form prescribed by the department shall permit~~
34 ~~the company to identify any information that is a trade secret.~~

35 (d) The following shall be exempt from disclosure:

36 (1) Free samples of prescription drugs intended to be
37 distributed to patients.

38 (2) The payment of reasonable compensation and
39 reimbursement of expenses in connection with bona fide clinical
40 trials. As used in this paragraph, “clinical trial” means an

~~1 approved clinical trial conducted in connection with a research
2 study designed to answer specific questions about vaccines, new
3 therapies, or new ways of using known treatments.~~

~~4 (3) Any gift, fee, payment, subsidy, or other economic benefit
5 the value of which is less than twenty-five dollars (\$25).~~

~~6 (4) Scholarship or other support for medical students,
7 residents, and fellows to attend a significant educational,
8 scientific, or policymaking conference of a national, regional, or
9 specialty medical or other professional association if the recipient
10 of the scholarship or other support is selected by the association.~~

~~11 (e) As used in this section:~~

~~12 (1) "Pharmaceutical marketer" means a person who, while
13 employed by or under contract to represent a pharmaceutical
14 manufacturing company, engages in pharmaceutical detailing,
15 promotional activities, or other marketing of prescription drugs in
16 the state to any physician, hospital, nursing home, pharmacist,
17 health benefit plan administrator, or any other person authorized
18 to prescribe, dispense, or purchase prescription drugs. The term
19 does not include a wholesale drug distributor or the distributor's
20 representative who promotes or otherwise markets the services of
21 the wholesale drug distributor in connection with a prescription
22 drug.~~

~~23 (2) "Pharmaceutical manufacturing company" means any
24 entity which is engaged in the production, preparation,
25 propagation, compounding, conversion, or processing of
26 prescription drugs, either directly or indirectly by extraction from
27 substances of natural origin, or independently by means of
28 chemical synthesis, or by a combination of extraction and
29 chemical synthesis, or any entity engaged in the packaging,
30 repackaging, labeling, relabeling, or distribution of prescription
31 drugs. The term does not include a wholesale drug distributor or
32 pharmacist.~~

~~33 (c) For purposes of receiving additional guidance regarding
34 practices that constitute "inappropriate marketing," the
35 department shall refer to the Compliance Program Guidance for
36 Pharmaceutical Manufacturers, issued by the United States
37 Department of Health and Human Services' Office of the Inspector
38 General.~~

~~39 110424.85. Notwithstanding Section 111825, any person who
40 violates this article or any regulation adopted pursuant to this~~

1 *article shall, if convicted, be subject to a fine of not more than ten*
 2 *thousand dollars (\$10,000) per violation. If the violation is*
 3 *committed after a previous conviction under this article that has*
 4 *become final, the person shall be subject to a fine of not more than*
 5 *twenty thousand dollars (\$20,000) per violation. Every individual*
 6 *action that violates this article shall be considered a separate*
 7 *violation.*

8 SEC. 2. Section 14105.37 is added to the Welfare and
 9 Institutions Code, to read:

10 14105.37. (a) (1) During each negotiation with a
 11 manufacturer regarding the purchase of ~~a drug or drugs~~ *one or*
 12 *more drugs or devices* that are used to treat a life-threatening
 13 condition, the department shall require the manufacturer to
 14 disclose the aggregate marketing costs for the ~~drug or drugs~~ *drugs*
 15 *or devices* that are the subject of that negotiation. The department
 16 shall keep this data confidential, although the department, on an
 17 annual basis and without identifying any manufacturer in any way,
 18 shall provide aggregate *industry-wide* marketing cost information
 19 *by therapeutic category* to the relevant committees in both houses
 20 of the Legislature and to the Legislative Analyst.

21 (2) *The department shall, for purposes of this subdivision,*
 22 *determine what constitutes marketing costs.*

23 (b) *For purposes of this section, “life-threatening” means*
 24 *either of the following:*

25 (1) *Diseases or conditions where the likelihood of death is high*
 26 *unless the course of the disease is interrupted.*

27 (2) *Diseases or conditions with potentially fatal outcomes*
 28 *where the end point of clinical intervention is survival.*

29 (c) *Except as otherwise provided in subdivision (a), the data*
 30 *collected pursuant to this section shall not be subject to disclosure*
 31 *under the California Public Records Act (Chapter 3.5*
 32 *(commencing with Section 6250) of Division 7 of Title 1 of the*
 33 *Government Code).*

34 SEC. 3. No reimbursement is required by this act pursuant to
 35 Section 6 of Article XIII B of the California Constitution because
 36 the only costs that may be incurred by a local agency or school
 37 district will be incurred because this act creates a new crime or
 38 infraction, eliminates a crime or infraction, or changes the penalty
 39 for a crime or infraction, within the meaning of Section 17556 of
 40 the Government Code, or changes the definition of a crime within

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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